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10/552,357

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Basil D. Favis

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SUITE 2200

MONTREAL, QC H3A 3H3

CANADA

EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

02/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/552,357 | Applicant(s) FAVIS ET AL. | |
| | Examiner BETHANY BARHAM | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 6-12, 14-36, 38, 40 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13 and 44 is/are rejected.
- 7) ☒ Claim(s) 37, 39, 41 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Applicant's response and amended claims filed on 11/20/09 is acknowledged. Claims 1-44 are pending. Claims 1-5, 13, 37, 39, 41 and 43-44 are rejected or objected to.

NEW OBJECTIONS/REJECTIONS

Claims 37, 39, 41 and 43 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only (ie "any one of claims 1-5 or 13"). See MPEP § 608.01(n). Accordingly, claims 37, 39, 41 and 43 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 13 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independent claims 1 and 13,

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from which all other claims depend, have been amended to claim “a majority of pores has a diameter within at most +/- 50% of the chosen pore diameter” for which there is no description in the instant specification for “at most +/- 50%”. In fact nowhere in the instant specification does the phrase “at most” appear, and certainly not in the section of [0051-0098] pointed to by Applicant. This is a new matter rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5, 13 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims 1 and 13, from which all other claims depend, have been amended to claim “a majority of pores has a diameter within at most +/- 50% of the chosen pore diameter”, what does the phrase “within at most +/- 50% of the chosen pore diameter” mean? Since this phrase is not described in the instant specification, it is assumed for the purpose of examination that so long as the 'majority' of the pore sizes are within +/- 50% of the chosen pore diameter that the limitation of the claims are met.

For example using instant claim 2 a pore diameter of 20nm-500 microns, it means that so long as the majority of the pores are between 10nm-750 microns then the limitation is met, since 10 nm is equivalent to -50% of 20nm and 750 microns is equivalent to +50% of 500 microns.

MAINTAINED REJECTIONS

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 19, 26, 28, 30 of copending Application No. 12/093712. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a porous material comprising essentially continuous pore network for use as tissue engineering, controlled release, and implantable medical devices.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Washburn et al (cited in IDS and ISR).

The instant claims are drawn to a microporous polymeric article comprising an essentially continuous porosity with a controlled void volume from 10 to 90%, wherein pore diameters show a unimodal distribution set to a predefined unimodal peak location corresponding to a chosen pore diameter, and wherein a majority of pores has a diameter within at most +/- 50% of the chosen pore diameter.

- Washburn et al teaches porous scaffolds for tissue engineering using poly(caprolactone) with poly(ethylene oxide) results in continuous networks of polymer and void spaces, a pore size of 20-150 or 10-100 microns and 70% or 50% voids (abstract, pg. 25 col. 1, and pg. 26 col. 1, Figure 5) (meeting the limitations of claims 1-2 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claims 13 and 44 are met by Washburn et al.

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- Figure 5 teaches void space with 50 micron size (meeting the limitations of claims 3-4).
- Tissue engineering and implants are taught as uses for the porous scaffolds of Washburn et al (abstract, pg. 20).

Claims 1-5, 13, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,856,367 ('367) (cited in IDS).

- '367 claims a biocompatible porous matrix (such as PLGA) with a network of interconnecting pores and a void volume of 20-97% and pore diameters of 0.5-50 microns (claims 1-7, Example 6) (meeting the limitations of claims 1-5 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claims 13 and 44 are met by '367.
- '367 teaches tissue regeneration and medical implants (col. 5, lines 10-35).

Claims 1-5, 13, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by 6,281,257 ('257) (cited in 892).

- '257 claims a biocompatible porous matrix (such as PLGA) with a network of interconnecting pores and a void volume of at least 80% and pore diameters of 50-200 microns (abstract; col. 2, lines 20; col. 8, lines 19-20) (meeting the limitations of claims 1-5 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process,

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determination of patentability is based on the product itself" thus the product limitation claims 13 and 44 are met by '257.

- '257 teaches tissue regeneration, platforms, matrices and medical implants (col. 1, lines 10-45).

Claims 1-4, 13, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by 2002/0005600 ('600) (cited in 892).

- '600 claims a biocompatible porous matrix (such as PLGA) with a network of interconnecting pores and a void volume of at least 80% and pore diameters of 100-500 microns (claims 42-43 and abstract; [0002, 0064, 0091]; Fig. 6) (meeting the limitations of claims 1-4 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claim 13 is met by '600.
- '600 teaches tissue regeneration, controlled release and medical implants (abstract, col. 1, lines 10-45).

Response to Arguments

Applicant's arguments with respect to claims 1-5, 13, 37, 39, 41 and 43-44 have been considered but are not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant argues that the ODP is provisional and does not wish to address it at this time, however acknowledges that the

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Examiner may continue to make the rejection as long as there are conflicting claims, as such this rejection is hereby maintained. Further, Applicant argues that the prior art Washburn et al, '367, '257, or '600 do not "provide quantitative measurements of continuity as determined by solvent extraction/gravimetry", do not "provide quantitative measurements of the effective void volume fractions" and do not "collect measurements over a statistical population". Applicant argues that the SEMs in the prior art are cross sections or 2-D analysis and do not read on the three-dimensional structure of the instant 'continuity'. The Examiner respectfully points out that the prior art teaches the same product, a continuous network of micro-porous polymer scaffolds for use in tissue engineering, etc with overlapping void volumes and micron pore sizes and Applicants measurements (ie by solvent extraction/gravimetry, etc) do not give it patentable weight, since it is the same composition, as adding a characterization to a prior art patented invention is not patentable.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-61755. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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